UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MASTER FILE NO. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

ALFREDA LEE, et al., V. ETHICON, INC., et al.
CIVIL ACTION NO. 2:12-cv-01013

SUSAN THAMAN V. ETHICON, INC., et al.,
CIVIL ACTION NO. 2:12-cv-00279

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DEPOSITION OF

JOHN R. MIKLOS, MD

April 8, 2016

10:52 a.m.

3575 Piedmont Road, NE

Atlanta, Georgia

Heather Brown, RPR

CCR-4759-4284-5258-1376
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Page 10

doing, what I will call more minimally invasive procedures, beginning in the 90s with regard to laparoscopic procedures; is that true?

A. Yes. I would say that's true.

Q. Can you tell me -- just give me an overview of what your current practice is like. Are you straight female pelvic medicine or are you doing other things like, you know, laparoscopic procedures, vaginal rejuvenation, whatever it is?

A. Yes. Well, I'm a urological gynecologist. Which -- and I'm board certified in female pelvic medicine and reconstructive surgery. I did a two-year fellowship in that, so that is my specialty, but I also did two years of minimally invasive -- same concept -- reconstructive pelvic surgery. On top of that, I spent a couple months learning cosmetic vaginal surgery.

So my practice is dedicated to the reconstruction of female pelvises. Dedicated to women, only urogynecologic and gynecologic cosmetic surgical procedures. So it's strictly dedicated to that, and it's been that way since 1995. No obstetrics, no routine OB/GYN, no pap smears -- maybe one or two pap smears a year.

Most patients are either referred to me -- they find me, and they're not permanent patients. They come usually for an evaluation, diagnostic, treatment, if necessary, and then hopefully they move on.

Page 11

Q. Do you still do a fair amount of laparoscopic procedures?

A. Absolutely.

Q. Would it be fair to say that the most influential variable in outcomes is the skill set of the surgeon?

A. Repeat the question, please.

Q. Sure. Would it be fair to say that the most influential variable affecting patient outcomes following surgery is the skill set of the surgeon?

A. I've never looked at that scientifically, but I believe that the skill of the surgeon plays one of the most important roles, yes.

Q. For instance, I know you are well-published and have a good reputation -- a very good reputation in laparoscopic surgical procedures. There are other surgeons who have access to those same laparoscopic trocars, you know OR set up, et cetera, but who do not have results as good as yours as published. What would you attribute that to, if anything, beyond the skill set of the surgeon?

A. Oh, multiple things. It's obviously education, training, commonsense, pragmatism, logic doing surgery. I can even equate it back to just how I was raised. But that being said, it also requires that -- well, let me put it this way: I have the great fortune of operating all over the world, and having the appropriate equipment is extremely important, too.

Page 12

So it's a combination of things; skills, training, education, knowledge, and good equipment, and the appropriate patients, too. It's a lot -- you'll have better success usually in patients that are maybe healthier, not -- have a lower body mass index --

Q. Right.

A. -- and not as many previous surgeries.

Q. Okay. Can you tell, me what's your current treatment modalities you use for the surgical treatment of female stress urinary incontinence?

A. Sure. If I'm going to isolate it a little bit, because it changes and it is a dynamic situation, currently I use primarily three different modalities: Laparoscopic Burch; Johnson & Johnson Gynecare TVT Exact, or the retropubic sling; and a minimally invasive single-incision sling on occasion -- which is made by Coloplast -- it's called an Altis, A-l-t-i-s. And the general makeup has changed dramatically over the last three years. Dr. Moore, my partner, has recently gone through our cases with one of our research assistants and found that we were approximately 75 to 80 percent synthetic slings three years ago and currently, last year, we were at 77 percent Laparoscopic Burch again.

Q. Okay. The Coloplast Altis, I'm not familiar with that sling. I know you had done, in the past, the MINI ARC, true?

Page 13

A. Yes, MINI ARC.

Q. Coloplast Altis, is that a polypropylene sling or is it made of some other material?

A. Polypropylene.

Q. Is that a Type One macroporous polypropylene mesh, monofilament?

A. Yes.

Q. When you do your Lap Burch, do you use permanent sutures?

A. Yes.

Q. What type?

A. Cortex.

Q. How many?

A. I do a Tanaga Modification, and that's four sutures.

Q. The Coloplast Altis, of those three procedures, is that the one you do the least by volume?

A. Yes.

Q. Are there certain patient cohorts or categories you reserve that Mini-Sling for or stay away from? Such that, obviously I'm not going to do that on a recurrent patient or an ISD patient?

A. Very good. I tend to shy away if they have -- the word Intrinsic Sphincter Deficiency or ISD, depending on who you talked to, encompasses -- it can encompass every patient. Urologists will tell you every patient has some ISD, it's a

Page 26

technique?
A. Can you repeat the question?
Q. Sure.
A. You mean from me or was the company?
Q. No, no, no. Really, I'm talking about you and your art, your field.
A. Oh, I see.
Q. In your art, in your field, did you -- was there a movement by surgeons in general towards more and more minimally invasive procedures to treat these conditions, such that there was a trans -- a retropubic approach, then it moved to the transobturator, and then it ultimately went to Mini-Slings?
A. I think historically and retrospectively that's pretty self-evident. And, yeah, I think most companies were attempting that with the idea that TVT, transobturator, now single-incision slings, and even at the same -- simultaneously open incisions versus transvaginal and laparoscopic for prolapse and -- yeah, that was the attempt. The balance is success, morbidity, and are they equally effective and less morbid than the predecessor, or are they more effective and less morbid? You can't have same effect -- efficaciousness and have the same morbidity and expect it to be a great operation, because you're not achieving anything other than it's a smaller incision.
Q. Right. Did it make sense to you to go towards a more

Page 27

minimally invasive insertion technique by way of Mini-Sling approach based upon your experience and knowledge of your art over two decades?
A. The concept made sense. Thus, the reason that I did 28 TVT-Securs.
Q. Twenty-eight?
A. Yeah. But that was also based on trusting people that I knew, my contemporaries, my colleagues, and some of these people are the leaders in the world that we communicate just -- Michele Cosson, Vince Lucente, Dennis Miller, so these are people that we talk to routinely. And when Vince told me, John, I'm getting great results, I mean, I had nothing else to believe but he was getting great results. And the concept is right; smaller incision, if I can get the same results, what's the downside for the patient? And that was the goal.
Q. Okay. Obviously, by reading your report, you're of the opinion that overall, the TVT-Secur is not as effective as the TVT retropubic device or the TVT-O full-length slings; is that a fair statement?
A. That's an absolutely fair statement, and I think that's proven from day one. Including Dr. Lucente, who does 77 patients, I do 28, we combine our data, he has a 68.5 percent cure rate, I have a 79 percent cure rate at good ol' 6 weeks, which is nothing in the world of surgery. At that point, realizing a TVT is 90 to 95 percent successful at one year and

Page 28

I'm getting an 80 percent cure rate at 6 weeks -- that cure rate never gets better, it only goes down -- I had to stop because it wasn't the right thing for my patients. It wasn't beneficial, it wasn't efficacious, and it wasn't the right thing to do. Now, Vince still believed -- and it's his right to believe what he wants and he's a good surgeon -- he told me, he said nope, John, I'm telling you it's a great operation. So he continued down that path.
Q. So you've obviously read studies on the TVT-Secur reporting its clinical effectiveness and safety in women for the treatment of stress incontinence, true?
A. Yes.
Q. And there are studies that report satisfactory efficacy with TVT-Secur, even level one data, correct?
A. Yes, but they're few and far between. There's not a ton of studies that say that the cure rate is over 90 percent. I mean, we can sit there and basically say, study number one, Mauro Cervigni and Bursconi, 24 months out, 89.5 percent cure rate. Okay, that's a decent study. I know Mauro Cervigni, I've operated with him in Rome. I like him, he's a good guy, he's pretty honest. Not a bad study.
Study number 2, we can then look at the Neuman study. I don't know Dr. Neuman from Israel, but he has a 91 percent cure rate at three years out, so those are your two best at this point. Except for Luo, who's from China.

Page 29

Now, Luo and his multi-prospective randomized chemical trial of three different studies, he has a 100 percent cure rate, 99.5 percent cure rate, 98.5 percent cure rate. I'm not saying it's not possible, but it gives me a little angst when anybody has a 100 percent cure rate on an operation 12 months out of surgery. I mean, it's a little hard to believe for me. So we still have a couple other studies in the 80 to 90 percent range and that would be -- that I'm aware of and that is Kim from Korea, who sits out at 88 and 89 percent using the UNH technique and then you also have Kandawalla, who has an 84 percent cure rate at 14 months out.
Now, the majority of these studies are still not in the ballpark of the TVT and we're talking about five studies, there may be others. What's important is the longest term studies, Tomaselli at five years out, shows a cure rate of TVT-Secur sitting down the 67 percent range and then Masada study, five years out. Those are the two longest studies that I can remember right now and they're sitting out at 65 percent cure rate. And then when you do the prospective randomized chemical trials, you do the metaanalysis, you do the Cochrane Reviews, you have somebody like Navarre and Steven Jeffries from South Africa looking at all these studies, specifically the randomized chemical trials pulling out the TVT-Securs and saying overall, the mass majority of the highest form of scientific evaluation, that the TVT-Secur is not as effective

Page 30

as the TVT-O, inside-out or the TVT -- TOT -- or a TVT-O inside-out, TOT outside-in, and the retropubic slings.

So, again, you're always going to have studies that show great cure rates. What I find hard to believe is that I'm sitting with Vince Lucente, who's the leader in the world, in the world, and his cure rates are 69 percent after 77 patients --

Q. Right.

A. I mean, this is somebody well respected and was the number one leader, the key opinion leader, with maybe the exception of Carl Gustav Nilsson from Finland and Walter Artibani from Verona, Italy, and even those two guys stopped doing the procedure. I've never figured out the reason why, even though they were the first to do the studies in their respective country, because I don't find it in the internal documents, but it sure is crazy -- then we go over to Australia, I know Malcolm Frazer, I know Bruce Farnsworth, I know Marcus Carey, there again Bruce Farnsworth -- I'm sorry, Malcolm Frazer is getting a cure rate of 35 percent. There's a problem with the procedure.

In maybe a few doctor's hands they can get decent surgery, decent cure rates, but for the mass majority based on the literature, based on the internal documentation, based on depositions, based on the prospective randomized chemical trials, based on the metaanalysis, Cochrane Reviews,

Page 31

it's not there.

Q. You mentioned a paper by Tomaselli, and I think that's the one you were referencing.

A. Yeah. Wait a second. Is this the 2015 or the 2011?

Q. This is the '15. You mentioned a five-year follow up.

A. Yeah.

Q. So I was just making sure you had that.

A. Yeah. 2015, five-year.

Q. So in this study, this was one where statistically there wasn't a difference in the efficacy between the full-length and the TVT-Secur?

A. You are absolutely right. Statistically, it was not different and I believe it was 65 versus 82, let me just see where it is here. With objective cure rate, 82 versus 68. Absolutely statistical analysis, it is not statistically significant, but he makes sure that he well mentions that it's the downward trend. It's lower-end. What's really amazing, if you look at the long-term follow-up studies, if you hit five years, both of them are in the 60 percent range. Most studies for TVT retropubic, you hit five years, it's 83, 84, 85 and above. So I'm not saying -- and I think even Tomaselli is sort of hitting on here, saying it's not significant but, boy, it's not what we expected. It's a good study.

Q. Yeah. So there are surgeons, though, who got good

Page 32

results with TVT-Secur, correct?

A. Yeah. What's interesting --

Q. Is that a yes?

A. Yes.

Q. Okay.

A. What's interesting, though, they're not the surgeons that I would think that would be getting the great results because they're not the true key opinion leaders and the leaders throughout the world. How is it it's fly-by-nights, they wouldn't like that, but they're not the people that led the way or the true pioneers or the true pioneers of minimally invasive surgery and sling surgeries?

Q. Well, you mentioned about this surgeon, Luo, I think in Korea?

A. No. Not Luo, Kim.

Q. Kim, sorry. Oh, Kim.

Dr. Kim who has success rates, I think you mentioned of around 100 percent --

A. No, no. Luo, L-u-o, in China.

Q. Okay. Luo in China. All right. So I was --

A. I don't know if that's how you pronounce it, but it's L-u-o.

Q. You're fine. So Luo, let me rephrase. So you mentioned the surgeon Luo, a surgeon in China who reported very good rates with TVT-Secur, right?

Page 33

A. Yeah, that's what he reported.

Q. Have you ever operated with Dr. Luo?

A. No, I have not.

Q. So other than just the fact that his rates are basically almost 100 percent or 100 percent, you don't have any, I would say, personal or first-hand knowledge as to that surgeon producing false data?

A. Absolutely not. And he may truly have a 100 percent cure rate. But it's hard for me to believe that a company like Johnson & Johnson, Gynecare, Ethicon would promote a product that they didn't have any studies before they released it. This stuff came out later and this is a study that's much later than when they released their product, and their key opinion leaders can't get that type of result. I'm not saying Dr. Luo can't get that result, but I'm saying it's the few and far between that can.

Q. Who is the professor in Italy who had good results? Who was the first study that you mentioned?

A. Mauro Cervigni

Q. How do you spell that?

A. C-e-r-v-i-g-n-i, I believe. And actually it was his -- he's the senior author, it's a last name on the list. The first name would be Bersconi, B-e-r-s-c-o-n-i, I believe.

Q. Are they good surgeons according to your knowledge of them or reputation?

Page 46

A. That was the Masada, I believe.
Q. Do you know offhand, was that an individual study or a systematic review or --
A. Gosh, I believe it was a systematic review. We can look it up, though. Do you have a copy here?
Q. I don't think I have the Masada to be honest with you. I don't want to get you bogged down because I only have limited time.
A. Okay.
Q. But if Masada is the one you're relying on, that's fine. I'll go figure it out. I'll find it.
A. Also looking at the Cochrane Review by Steven Jeffries and his team where basically they say at the end there's an increased rate of --
Q. Did you look to see whether that was statistically significant?
A. No.
Q. And numerically how much of a different rate?
A. Yeah, that's one of the problems. The incidents of these complications are so low and most studies actually didn't look at the difference and one of the down sides of this study, and this is from years of experience looking at the erosion rate --
Q. Right.
A. -- is the erosion rate, from my perspective, my

Page 47

experience, my knowledge, my expertise in taking out over 800 to 1,000 pieces of mesh, is that it goes undiagnosed. Because even if you look at Piet Hinoul's study, they talk about adverse events. But in the primary, secondary endpoint, it doesn't say we're going to look for mesh extrusion, it doesn't say that. You gotta delineate, not just an adverse event. So often when people are getting examined -- a lot of these times when you're examining a patient, it's not just visualization, it's palpation.
Q. Right.
A. Because of the ruga of the vagina, the waves, a lot of times you don't see it. Every patient that I took out who had mesh extrusion, had a previous surgeon that told them there's nothing wrong with you. So it is dramatically and drastically underreported.
Q. Was that number 7, Doc?
A. Yes, it is.
Q. You would agree that there are numerous studies including high level randomized control trials that do not show a statistically significant increased risk of mesh extrusion or exposure with the TVT-Secur, correct?
A. Yes, I do agree. But also, I want to state that most studies actually didn't clarify to the primary, secondary endpoint in their study. It's an incidental finding. And number 2, it goes undiagnosed over and over again. I know that

Page 48

personally from my practice and having the largest paper in the world on removing mesh.
Q. So this is a paper I assume you're familiar with. This is the SGS, who did their systematic review and metaanalysis on the various surgical options to treat incontinence. Are you familiar with this paper?
A. It's been a while since I've read this.
Q. I just have a couple questions. Let's -- do you put more weight into systematic reviews and metaanalysis than an individual RCT? I'll ask you -- this is where I'm going --
A. Yeah.
Q. I'm sure you've heard Doctors of the Oxford Levels Evidence Pyramid.
A. Yes.
Q. Something you were probably taught in -- actually I saw you did an undergrad in the sciences so you probably knew about this even in your college sciences.
A. Probably not.
Q. Okay. What number are we up to?
A. This is 8.
Q. Okay. So this is the Oxford Levels of Evidence and you see at the top they have systematic reviews. Metaanalysis has a higher quality of evidence before individual RCTs and things of that nature.
(Whereupon Exhibit Miklos 8 was marked for

Page 49

identification.)
A. Yes.
Q. Is that something you agree or disagree with?
A. Generally, I agree with it.
Q. Okay.
A. I mean, I'm sure there's always exceptions to the rules and you have to take in your own personal experiences and your own education and knowledge but, generally, I agree with it. Generally.
Q. Yeah. For the application -- that's not the right word. Obviously, you're always going to bring into bear your personal experience, knowledge, and training, correct?
A. Yeah. It's a little more complicated than that, though, sometimes. You can tell me laparoscopic sacrocolpopexies are not efficient, but you haven't been in my OR. And that's not being arrogant, it's being honest. And people will look at me, and they'll say, just like the Neuman study or something, well, your cure rates are a little higher than most or your experience, you have less complications so I can't fully -- but this is the general, I would say, with the quality of evidence, I agree the metaanalysis sits at the top.
Q. Individual opinion is anecdotal according to the levels of evidence, true?
A. Yes.
Q. If you look at Table 1, it's got all the different

Page 54

agree obviously that it wasn't defective in some surgeons hands, true?

A. No. I won't agree to that. Defective design entails that you're not going to get -- defective design to me means that your risk outweighs the benefit with the product that's in your hands. I personally used it on a cadaver and on the first cadaver I used it on, I knew it was defective. Number 1, the razor blade, exactly what it is, the insertion tip, is unprecedented. I have been around in courses, in operating rooms, and have used all other types -- many other types -- of TVTs, TOTs,TVT-Os and they're all the same. They're long, narrow tubes that are cylindrical, cylindrical with a conical tip usually. Now all of a sudden, you have a new device that has a razor blade on it and you're asked to make a 1 centimeter incision and you're delivered this razor blade device that cuts through tissue, including urethra potentially, bladder potentially, and periurethral tissue.

Not only is it unprecedented and it destroys tissue and increases -- we know with that type of trauma it's going to increase scar tissue. Now, the actual release of the device, the releasing mechanism was horrendous and this is documented in the internal documents. It was said that day in the operating room on the cadaver. Vince Lucente agreed with me. He said, yeah, they need to redo it, but there's secrets of doing it. You gotta jiggle it. If you jiggle it -- and we

Page 55

see this even -- Hinoul even says it. Hinoul was their employee and he's writing this stuff in his paper. He's saying well, yeah, it could dislodge. Yeah, you jiggle it, you're dislodging the insertion tip.

Q. Right.

A. That's the next problem, the insertion tip has never been proven. Then you have this polysorb which is vicryl -- is poly-p-dioxanone, basically it's an absorbable material that has never been utilized before in the pelvic floor.

And finally, the device itself, when you get that device it was unlike any other device. When you got a TVT, they gave you everything you needed almost. Everything that you can use to apply the mesh. This, you actually had to attach a straight hemostat to it or a needle driver.

Q. Needle driver.

A. Which was ridiculous because people were actually -- you can't control the trajectory of where this needle tip is going and then trying to get the release and insert and stay. And then the last thing is because you're pushing it in, you're not pulling it through like the TVT or TOT or the Abbrevo, you have difficulty adjusting the tension because you're just pushing. How tight is tight? So it's a completely defective design.

Q. So it's your opinion that it's defective because of those attributes, but we can agree that even with those

Page 56

attributes to which you find objectionable or defective, surgeons still can get good results with TVT-Secur as evidenced by peer reviewed public literature you are aware of, correct?

A. Absolutely. You can kill a rabbit with a stone, too, but not too many people can do it.

I mean, the bottom line is when you produce a product, you need a product that is reproducible -- gives you reproducible efficacious results with minimal morbidity that you can put in your surgeons' hands. Here we see a product that was not -- they couldn't reproduce the results. So there's some people that can do it, but this is not to the benefit of the patient. If we go and look at J & J's credo, which I haven't looked at in a while, patient care and the responsibility to the patient is first and foremost. This is -- I've got to be honest with you, honestly, if this is your mom, you wouldn't give her a TVT-Secur. You would not.

Q. So you're aware that they received complaints from some surgeons on Secur and they did various investigations and did -- came out with key technical points on TVT-Secur?

A. Yes. They received some complaints from some surgeons, yes.

Q. I mean it's in the Quality Board minutes that you've looked at and that I've looked at, correct?

A. The problem is -- here's what's amazing to me: I never knew -- I was a leader for TVT, I never knew there was a

Page 57

place I could complain to in the United States. I used TVT-Secur, nobody ever took my complaints. So why is it that only some people got to complain and I never got to complain?

Q. Are you telling me you weren't aware that you could make complaints to Ethicon or the FDA under the Maude Database for untoward outcomes you deemed to be potentially from a device?

A. I did not know, and I was a preceptor for Gynecare, that you could actually make a complaint -- I mean, I knew I could complain to the rep or the next time I saw him at a meeting, but I didn't know that you actually wrote it out and logged it out. I swear to God, I didn't know. It blows my mind because if I'm a leader in their field at the time TVT and potentially TVT-Secur -- if I would have liked the product, if I would have believed in it and I had good success, I would have been a preceptor for it. I never knew that I could complain. I just quit -- stopped using it at that point.

Q. You saw that they came out with these key technical points to try to make sure surgeons were using the correct pathways, using the correct insertion techniques, dealing with fixation and proper removal --

A. Yeah, I've seen this --

Q. -- without having the device back back out on you?

A. Yeah. I never understood when this was produced because I never saw a copy of this, so --

Page 58

Q. This was produced in 2007. You're familiar with the TVT-Secur DVD-ROMs that used to be out?
A. Yes.
Q. It starts with the presentation of the hand and there's a Secur in it and there's the IFU, hammock video, U video. There's various different files and animations that one could see and this was one of the files for both the U and the hammock approach. I'll represent to you, this was in the DVD I pulled down the other night from May 2007.
A. Okay.
Q. Honest.
A. I believe you.
Q. It was cleared and approved by, internally, in I think March -- late March of 2007. That's another representation I'll make to you.
A. Okay.
MR. MATTHEWS: By Ethicon?
MR. SNELL: By Ethicon, exactly. A copy review is what that --
MR. MATTHEWS: When you start throwing words around like cleared and approved --
MR. SNELL: Right.
MR. MATTHEWS: -- you know my antenna goes up.
MR. SNELL: That's fine.
A. What I don't understand --

Page 59

Q. (By Mr. Snell) Well, my question is, have you reviewed this document forming your opinions?
A. No, I haven't. If I have, I don't recall it, and I started reviewing the documents back in October, a lot of this stuff. So, is there a specific area? I just don't remember this specifically.
Q. Okay. I was going to ask you about it if you had reviewed it but if you haven't, then I'm not going to waste your time because we've only got a couple more minutes.
A. Okay.
Q. How about this: Hypothetically, if Ethicon put this out to surgeons, key technical points trying to help them understand proper placement, fixation, you know, withdrawal of the device so it doesn't back out and get loose, was that something you would approve of as being a good step towards mitigating a problem that they've seen?
A. I think it's the first step. But if this was so darn important, why didn't they change your IFU? You have Dave Robbins saying the most important part of this surgical technique is that everybody should adhere to the IFU. He makes that statement in the internal documents. And then you have Ramy Mahmoud who sits there and says, who's the ex-CMO of Ethicon, he's sitting there saying the same thing, the training is so important. And Mark Gill saying the same thing, that we're having problems with our training. If it were so

Page 60

important, they should have retrained everybody. But we saw that they didn't retrain people because there was cost constraints.
If they really believed in patient care, and if they really believed in the quality of surgery for the patient -- I still can't get why Vince Lucente, here's your leader in the world and he can't get these great cure rates. And he came up with all different ideas. Where's his malleable device? I remember him talking to me about this at the SGS meeting, he goes well you gotta put a malleable. I said where's this in IFU? Where's the literature -- where is it from the company saying we should use the malleable device? Well, it's my trick and technique. If it was so important, then why wasn't it general common knowledge.
Listen, when there's a bad drug on the market, I get a letter in the mail. I don't even use these drugs and I get letters in the mail. I never remember getting anything that told me how from a mailer and I saw nothing in internal review because I was very interested, did Gynecare ever send out to their surgeons or all surgeons this change of technique.
Q. So based on the investigation you did -- I want to make sure I understand this. It's your understanding that Ethicon did not invest in retraining surgeons after these issues arose with regard to TVT and its efficacy or the device backing out?

Page 61

A. There were minor issues where they would -- they sent to the engineer like -- I mean if it was a major issue, they wanted to send Dan Smith, the engineer that actually produced TVT-Secur, they sent him to Germany to train the doctors, which is sort of inappropriate. You're an engineer, you don't really do the surgery on live patients, and you better not be. Then they offered to send him to Australia, which was nice of them, but by then they'd already taken it off of the regulatory list, they put a block on it. So I don't ever remember anybody ever coming back to me and saying hey, let's retrain you and let's show you how it's done. One cadaver lab and boom, you're on your way. I never even got to go to somebody's operating room.
Q. Did anyone ever turn you down for training at Ethicon or did you ask for training and they wouldn't allow you to do it?
A. No, because I didn't know at the time that this existed.
Q. Oh, no. I'm saying was there ever an occasion where you wanted to be retrained on something and you expressed that to someone at Ethicon and they said no?
A. No, because that's the 28 cases -- when I get an 80 percent cure rate, and Vince, the leader in the world, gets a 69 percent, I can't possibly believe that you guys -- he's the leader, he's the man. He taught Australia. I mean, the only person above him would have been Carl Gustav from Finland and

(Pursuant to Rule 30(e) of the Federal Rules Of Civil Procedure and/or O.C.G.A. 9-11-30(e), Signature of the witness has been reserved.)

STATE OF GEORGIA:
COUNTY OF GWINNETT:

I hereby certify that the foregoing transcript was reported, as stated in the caption, and the questions and answers thereto were reduced to typewriting under my direction; that the foregoing pages represent a true, complete and correct transcript of the evidence given upon said hearing, and I further certify that I am not of kin or counsel to the parties in the case; am not in the employ of counsel for any of said parties; nor am I in any way interested in the result of said case.

____
Heather Brown, RPR
CCR 4756-4284-5258-1376

DISCLOSURE OF NO CONTRACT

I, Heather N. Brown, Certified Court Reporter, do hereby disclose, pursuant to Article 10.B. of the Rules and Regulations of the Board of Court Reporting of the Judicial Council of Georgia, that I am a Georgia Certified Court Reporter; I was contacted by the party taking the deposition to provide court reporting services for this deposition; I will not be taking this deposition under any contract that is prohibited by O.C.G.A. 15-14-37(a) and (b) or Article 7.C. of the Rules and Regulations of the Board; and I am not disqualified for a relationship of interest under O.C.G.A. 9-11-28(c).

There is no contract to provide reporting services between myself or any person with whom I have a principal and agency relationship nor any attorney at law in this action, party to this action, party having a financial interest in this action, or agent for an attorney at law in this action, party to this action, or party having a financial interest in this action. Any and all financial arrangements beyond my usual and customary rates have been disclosed and offered to all parties.

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